DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

January 24, 2003

VIA FEDERAL EXPRESS

FACILITY ID #222911

Jeff Brewer
Senior Vice President of Operations
Montclair Baptist Medical Center
800 Montclair Road
Birmingham, AL 35213

Warning Letter No. 03-NSV-07

Dear Mr. Brewer:

An inspection of Baptist Imaging Center - Trussville was conducted on January 8, 2003 by a representative of the State of Alabama acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious compromise in the quality of the mammography services offered by this facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The recent inspection at this facility revealed the following Level 1 finding:

Level 1

The system to communicate results is not adequate for Baptist Imaging Trussville because:

- There is no system in place to provide timely lay summaries – *21 CFR 900.12(c)(2)*
- There is no system in place to communicate serious or highly suggestive cases as soon as possible – *21 CFR 900.12(c)(2)*

This specific deficiency noted above appeared on the MQSA Post Inspection Report which was sent to this facility by the state inspector along with instructions on how to respond to this finding. Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at this facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Direct Plan of Correction, charging your facility for the cost of on-site monitoring, seeking civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography. [See 42 U.S.C. §263b(h)-(j)]

In addition, you should also address the following deficiency that was also listed on the inspection report:

Level 2

1 of 7 random reports reviewed did not contain an acceptable assessment category for the findings – *21 CFR 900.12(c)(1)(iv)*

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and to promptly initiate permanent corrective actions.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations. Your response should include:

- The specific steps you have taken to correct the Level 1 and Level 2 violations as outlined in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record-keeping procedures relating to quality control or any other records that are appropriate to the noncompliance finding (NOTE: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies submitted).

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Alabama. Should you have questions regarding the technical aspects of this letter or concerning MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or though the Internet at http://www.fda.gov/cdrh/mammography/index.html.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

CED:krs